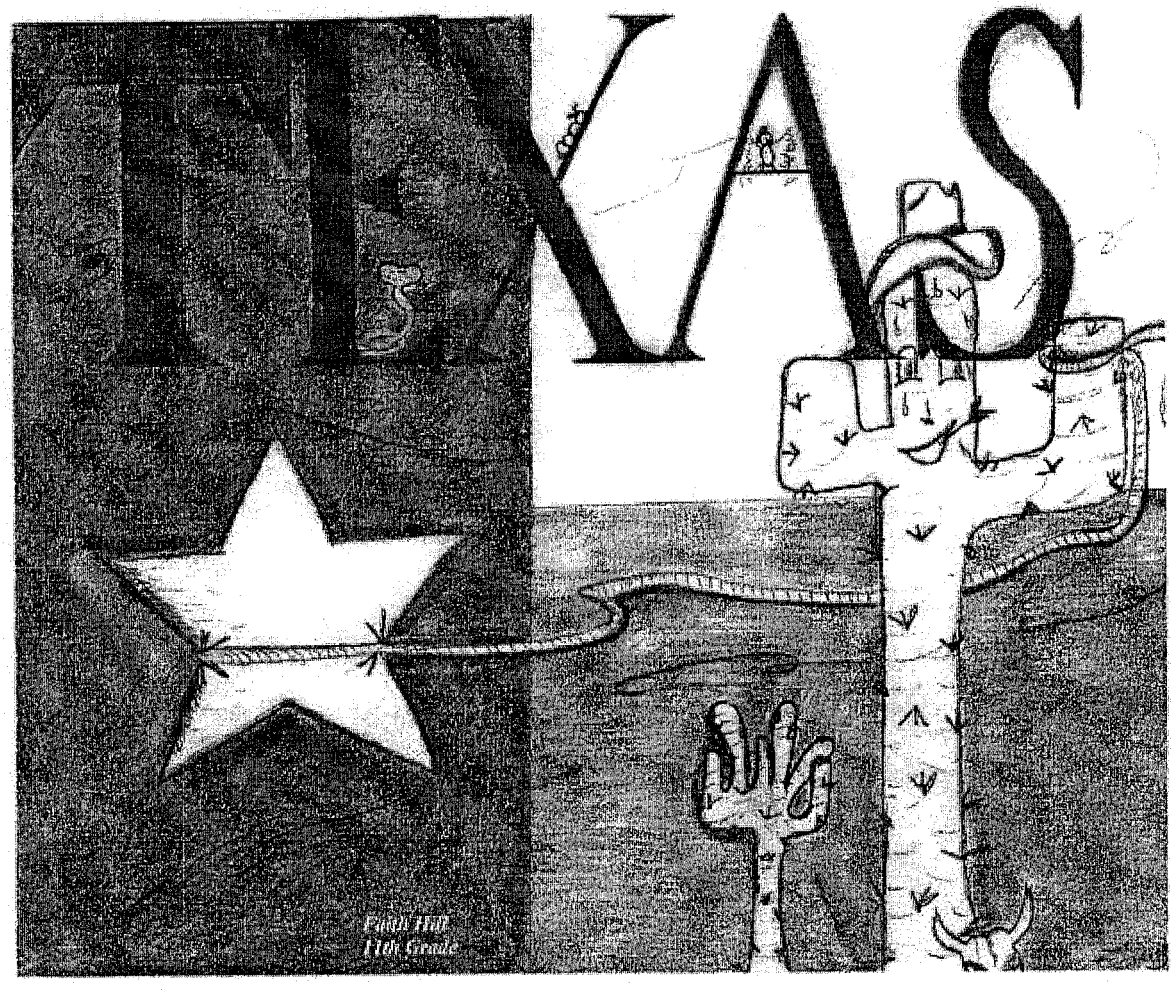
John Herl

TEXAS REGISTER

Volume 36 Number 51 *December 23, 2011* *Pages 8631 - 9102*



Under §2006.002 of the Government Code, a state agency proposing an administrative rule that may have an adverse economic effect on small businesses must prepare an economic impact statement and a regulatory flexibility analysis. The economic impact statement estimates the number of small businesses subject to the rule and projects the economic impact of the rule on small businesses. The regulatory flexibility analysis describes the alternative methods the agency considered to achieve the purpose of the proposed rule while minimizing adverse effects on small businesses.

HHSC collects very limited cost data from pharmacies that currently are enrolled in the Medicaid Vendor Drug Program. The minimal financial information collected from pharmacies during claims processing is insufficient to determine the size of the business. Specifically, HHSC collects data concerning the usual and customary price a pharmacy charges the general public for products reimbursed by Medicaid (see 1 TAC §355.8544) and, when required pursuant to an audit, pharmacy invoices for products reimbursed by Medicaid. Accordingly, HHSC is unable to determine whether or to what extent a non-chain pharmacy that is currently enrolled in the Medicaid Vendor Drug Program is a small business or micro-business.

Nonetheless, HHSC estimates that 996 independent pharmacies in Texas may be small businesses or micro-businesses and that the proposed new rules may have an adverse economic effect on some of these businesses related to the carve-in of pharmacy benefits into managed care capitation rates. The economic impact from the proposed rules, however, is uncertain, and the following analysis represents HHSC's best estimate of the potential adverse economic effect pharmacy carve-in may have on pharmacies across the state, including small and micro-businesses.

During the 2011 Legislative Session, HHSC informed the Legislature of anticipated cost savings that it hoped would result from the pharmacy carve-in. Those estimated cost savings (outlined in the Fiscal Note section above) result from efficiencies that the agency hopes would be achieved by changing the way HHSC pays for Medicaid pharmacy services. The marketplace will determine the amount of efficiencies that are actually achieved because a Medicaid managed care model necessarily involves negotiations of rates between managed care entities and providers, without rate-setting interference by HHSC.

HHSC estimates that 996 independent pharmacies in Texas that may be small businesses or micro-businesses will be affected by the proposed rules and may experience an adverse economic impact as a result of the pharmacy carve-in. The extent of the effect depends on the negotiations that occur between the MCOs and the pharmacies and on the number of pharmacies that already have a contractual relationship with a pharmacy benefits manager or MCO. Because, as noted above, the outcome of the negotiations are outside of HHSC's authority to control, the amount of adverse economic impact to pharmacies cannot be calculated with certainty. Another factor that makes the economic impact difficult to calculate is that a provider's revenue from the Medicaid program is contingent on the volume of Medicaid recipients it serves. HHSC cannot predict with certainty the future utilization of pharmacy benefits by the Medicaid population; however, HHSC believes that utilization management controls implemented by managed care organizations will result in lower utilization and therefore likely reduce pharmacy revenues.

Given these areas of uncertainty, HHSC used a set of MCO pharmacy reimbursement assumptions to estimate the amount of impact on those pharmacies that are likely to qualify as small or micro-businesses under the definitions in Texas Government Code §2006.001. The MCO pharmacy reimbursement assumptions were based on pharmacy reimbursement information provided by the MCOs. We then applied the assumptions to actual claims experience from fiscal year 2011, using a sample size that represented more than 37 million claims, in the current fee-for-service Vendor Drug Program (VDP) to arrive at estimated reimbursements to pharmacies in managed care. We then compared the estimated reimbursements to the actual VDP pharmacy cost experience. In general, we found that dispensing fees paid under managed care will be significantly less than under VDP, while ingredient costs under managed care will be greater than under VDP. These assumptions produced the following results:

(1) Overall pharmacy reimbursement under managed care will be 2.6% less than under VDP;

(2) Independent pharmacy reimbursement under managed care will be 6.0% less than under VDP; and

(3) Chain pharmacy reimbursement under managed care will be 0.3% less than under VDP.

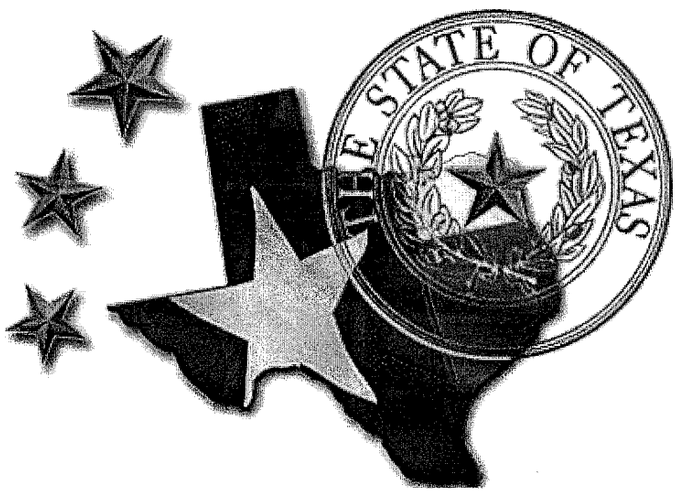
For purposes of this analysis, "independent pharmacies" were defined as all pharmacies with four or fewer store locations. HHSC recognizes that this definition of "independent" pharmacies likely results in a greater number of pharmacies than would qualify under Government Code §2006.001, which defines a "small business" as one that is independently owned and operated and has fewer than 100 employees or less than $6 million in annual gross receipts. HHSC does not readily have access to employment or financial data for these providers, and thus could not estimate the impact to the particular subset of independent pharmacy providers contemplated by the statute.

As stated in the background and justification section above, HHSC is required by state law to carve pharmacy services into managed care. In conducting the regulatory flexibility analysis required by Government Code §2006.002, HHSC recognizes that, while the proposed rules may have an economic effect on pharmacy businesses in the state, the rules do not actually regulate pharmacies. Participation by pharmacy providers and all healthcare providers in the Medicaid program is voluntary. The proposed rules do not impose duties or obligations on pharmacies and do not require regulatory compliance. Any "regulatory flexibility" HHSC could consider as an alternative to the pharmacy carve-in would fail to comply with the directive of the Texas Legislature in S.B. 7 to carve pharmacy services into managed care. However, HHSC did consider, but ultimately declined to implement at this time, the following options related to certain aspects of the managed care pharmacy benefit:

1) Mail order prescriptions. HHSC considered the potential cost savings and other likely impacts of requiring Medicaid recipients who are enrolled in managed care organizations to obtain all or most of their prescription drugs through mail order delivery. However, S.B. 7 and Rider 81 of the General Appropriations Act placed limitations on the use of mail-order pharmacies. The Legislature instructed that "the managed care organization may include mail-order pharmacies in its networks, but may not require enrolled recipients to use those pharmacies, and may not charge an enrolled recipient who opts to use this service a fee, including postage and handling fees(.)" S.B.7, Sec. 1.02, 82nd Leg., 1st C.S., 2011 (amending Tex. Gov't Code §355.005). Thus, while mail order can be offered as an option for members of an MCO,

Pharmacy Cost of Dispensing Survey
Statistical Summary
Texas Health and Human Services Commission

Characteristic	n: Number of Pharmacies	Average Total Prescription Volume	Average Medicaid Prescription Volume	Pharmacy Dispensing Cost per Prescription [1] — Measurements of Central Tendency — Means: Mean	Means: Weighted by Total Rx Volume	Means: Weighted by Medicaid Rx Volume	Medians: Median	Medians: Weighted by Total Rx Volume	Medians: Weighted by Medicaid Rx Volume	Other Statistics: Standard Deviation	95% Confidence Interval for Mean (based on Student t): Lower Bound	95% Confidence Interval for Mean (based on Student t): Upper Bound	95% Confidence Interval for Mean (based on Student t): t Value (with n-1 degrees of freedom)
All Pharmacies in Sample	1,263	82,292	841	$15.30	$10.88	$11.57	$10.80	$9.95	$9.47	$22.26	$14.07	$16.53	1.96
Non Specialty Pharmacies [2]	1,206	82,465	822	$12.82	$10.25	$10.12	$10.70	$9.83	$8.98	$10.21	$12.24	$13.39	1.96
Specialty Pharmacies [2]	57	78,631	1,229	$67.84	$24.81	$32.13	$30.74	$15.35	$15.35	$77.32	$47.32	$88.36	2.00
Non Specialty Pharmacies Only													
Affiliation:													
Chain	903	90,486	723	$12.10	$10.02	$9.06	$10.52	$9.55	$7.94	$8.73	$11.53	$12.67	1.96
Independent	303	58,563	1,120	$14.94	$11.34	$12.14	$11.19	$10.47	$11.36	$13.50	$13.42	$16.47	1.97
Location (Urban vs. Rural): [3]													
In State Urban	953	86,154	909	$13.38	$10.32	$10.17	$10.86	$9.81	$8.95	$11.25	$12.67	$14.10	1.96
In State Rural	253	68,570	497	$10.69	$9.94	$9.72	$10.16	$9.88	$9.48	$3.82	$10.21	$11.16	1.97
Annual Rx Volume:													
0 to 49,999	356	27,484	291	$19.19	$14.57	$15.54	$14.15	$12.67	$12.32	$16.57	$17.46	$20.92	1.97
50,000 to 89,999	452	69,904	549	$10.83	$10.76	$10.56	$10.59	$10.52	$10.22	$3.03	$10.55	$11.11	1.97
90,000 and Higher	398	145,909	1,609	$9.37	$9.25	$9.07	$9.47	$8.95	$8.00	$2.80	$9.10	$9.65	1.97
Annual Medicaid Rx Volume: [4]													
0 to 399	359	50,773	95	$17.68	$12.71	$14.69	$13.01	$11.26	$12.21	$15.62	$16.05	$19.30	1.97
400 to 999	399	72,615	340	$11.84	$10.85	$11.81	$10.71	$10.43	$10.58	$6.57	$11.19	$12.48	1.97
1,000 and Higher	448	116,634	1,835	$9.79	$9.07	$9.65	$9.25	$8.39	$8.85	$4.27	$9.40	$10.19	1.97
Medicaid Utilization Ratio: [4]													
0.0% to 1.0%	604	77,171	224	$13.26	$11.27	$11.10	$11.24	$10.65	$10.43	$8.06	$12.62	$13.91	1.96
>1.0% to 2.0%	303	80,254	593	$11.30	$9.66	$9.61	$9.90	$9.42	$9.37	$6.89	$10.52	$12.08	1.97
>2.0%	299	95,399	2,263	$13.45	$9.10	$10.05	$10.00	$7.94	$8.85	$15.46	$11.69	$15.21	1.97



Texas Health & Human Services Commission

Uniform Managed Care Terms & Conditions

pharmacies to also become Medicaid-enrolled durable medical equipment (DME) providers.

The MCO is responsible for negotiating reasonable pharmacy provider reimbursement rates, including individual MCO maximum allowable cost (MAC) rates, as described in Section 8.1.21.11, "Maximum Allowable Cost Requirements." The MCO must ensure that, as an aggregate, rates comply with 42 C.F.R. Part 50, Subpart E, regarding upper payment limits.

8.1.21.1 Formulary and Preferred Drug List

Section 8.1.21.1 added by Version 2.6 and modified by Version 2.13

The MCO must provide access to covered outpatient drugs and biological products through formularies and a preferred drug list (PDL) developed by HHSC. HHSC will maintain separate Medicaid and CHIP formularies, and a Medicaid PDL. The MCO must administer the PDL in a way that allows access to all non-preferred drugs that are on the formulary through a structured PA process.

The MCO must educate Network Providers about how to access HHSC's formularies and the Medicaid PDL on HHSC's website. In addition, the MCO must allow Network Providers access to the formularies and Medicaid PDL through a free, point-of-care web-based application accessible on smart phones, tablets, or similar technology. The application must also identify preferred/non-preferred drugs, Clinical Edits, and any preferred drugs that can be substituted for non-preferred drugs. The MCO must update this information at least weekly.

8.1.21.2 Prior Authorization for Prescription Drugs and 72-Hour Emergency Supplies

Section 8.1.21.2 modified by Versions 2.1, 2.6, 2.11, and 2.13

The MCO must adopt PA policies and procedures that are consistent with Section 8.1.8.1, "Compliance with State and Federal Prior Authorization Requirements."

The MCO must adhere to HHSC's PDL for Medicaid. Preferred drugs must adjudicate as payable without PA, unless they are subject to Clinical Edits. HHSC will identify Clinical Edits that the MCO must implement on the Vendor Drug Program website. The MCO may choose to implement additional Clinical Edits once these edits are approved by the Drug Utilization Review (DUR) Board, or alternatively by HHSC when appropriate, and posted on the Vendor Drug Program website

The MCO must submit new Clinical Edit proposals to HHSC for DUR Board review and approval. The MCO may also submit any proposed revisions to existing Clinical Edits to HHSC for DUR Board review and approval. HHSC will conduct preliminary review of these edit proposals and respond to the MCO before the next DUR Board meeting.

If a requested drug is subject to more than one edit (e.g., the drug is both non-preferred and subject to one or more Clinical Edits), the MCO must process all edits concurrently and independently so that each clinical edit is checked for approval.

8.1.21.7 Pharmacy Benefit Manager (PBM)

Section 8.1.21.7 modified by Versions 2.6 and 2.11

The MCO must use a PBM to process prescription claims.

The MCO must identify the proposed PBM and the ownership of the proposed PBM. If the PBM is owned wholly or in part by a retail pharmacy provider, chain drug store or pharmaceutical manufacturer, the MCO will submit a written description of the assurances and procedures that must be put in place under the proposed PBM Subcontract, such as an independent audit, to ensure no conflicts of interest exist and ensure the confidentiality of proprietary information. The MCO must provide a plan documenting how it will monitor these Subcontractors. These assurances and procedures must be submitted for HHSC's review during Readiness Review (see Section 7, "Transition Phase Requirements") then prior to initiating any PBM Subcontract after the Operational Start Date.

The MCO must ensure its subcontracted PBM follows all pharmacy-related Contract, UMCM, state, and federal law requirements related to the provision of pharmacy services.

Further, the MCO's reimbursement methodology for the PBM must be based on the actual amount paid by the PBM to a pharmacy for dispensing and ingredient costs. However, this prohibition on the industry practice known as "spread pricing" is not intended to prohibit the MCO from paying the PBM reasonable administrative and transactional costs for services, as described in UMCM Chapter 6.1, "Cost Principles for Expenses."

8.1.21.8 Financial Disclosures for Pharmacy Services

Section 8.1.21.8 modified by Versions 2.6 and 2.13

The MCO must disclose all financial terms and arrangements for remuneration of any kind that apply between the MCO or the MCO's PBM and any provider of outpatient drugs, any prescription drug manufacturer, or labeler, including formulary management, drug-switch programs, educational support, claims processing, pharmacy network fees, data sales fees, and any other fees. Article 9 of **Attachment A**, "Uniform Managed Care Contract Terms and Conditions," provides HHSC with the right to audit this information at any time. HHSC agrees to maintain the confidentiality of information disclosed by the MCO pursuant to this section, to the extent that the information is confidential under state or federal law.

8.1.21.9 Limitations Regarding Registered Sex Offenders

Section 8.1.21.9 modified by Version 2.6

HHSC's Medicaid and CHIP formularies do not include sexual performance enhancing medications. If these medications are added to the Medicaid or CHIP formulary, then the MCO must comply with the requirements of Texas Government Code §531.089 prohibiting the provision of sexual performance enhancing medication to persons required to register as sex offenders under Chapter 62, Texas Code of Criminal Procedure.

Figure V.3

Medicaid Managed Care Expansion
Comparison of Biennial Savings- Current Estimate to H.B. 1
($ in millions)

Managed Care Initiative	Current Estimate (June 2012 Forecast)		*House Bill 1 (May 2010 Forecast)	
	GR	**AF**	**GR**	**AF**
Expand Medicaid Managed Care in South Texas	($106.1)	($257.7)	($249.3)	($633.3)
Create a Dental Managed Care Model for Medicaid	(132.9)	(325.0)	(53.0)	(127.4)
Capitate Medicaid & CHIP Vendor Drug Programs	(9.1)	(23.5)	(0.7)	(4.4)
Include In-Patient Hospital Services in STAR+PLUS	1.1	2.7	(19.4)	(49.3)
Expand Medicaid Managed Care to Rural Service Areas	(13.0)	(31.8)	(20.2)	(51.8)
Capitate Medicaid in Urban & Contiguous Counties	6.1	14.8	(15.4)	(39.3)
Net Savings Administration	(9.3)	(24.9)	(21.8)	(44.4)
Subtotal Managed Care Savings	**($263.3)**	**($645.3)**	**($379.9)**	**($949.8)**
Impact of Lower Caseload and Cost Containment Initiatives	**($104.1)**			
Total Managed Care Savings	**($367.4)**			
Premium Tax Revenue	***$199.7***		***$238.0***	

** Rider 51 general revenue savings is $385.6 million, which is $5.7 million higher than the HHSC savings estimates. For consistency of comparison to original estimates, HHSC estimates are used in Figure 1.*

Provider Rate Reductions- Section 16

Article II, Special Provisions Section 16 required rate reductions for most providers beginning in September 2011. These reductions were in addition to rate reductions that many providers received in fiscal year 2011. Programs impacted include home and community-based services, hospice services provided in a nursing facility, Intermediate Care Facility for Persons with an Intellectual Disability (ICF/IID), most hospital services, DME, laboratory services, and certain other ancillary services. The estimated biennial savings for the Section 16 rate changes are $486.6 million in general revenue ($1,183.0 million all funds). This represents 85 percent of the H.B. 1 target of $571.3 million in general revenue. **Figure V.4** shows the rate reductions by provider type from fiscal year 2011 through fiscal year 2013.